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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,978

09/15/2006

David I. Cohen

51311-00009

2811

45200 7590 06/23/2010
K&L Gates LLP
1900 MAIN STREET, SUITE 600
IRVINE, CA 92614-7319

EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

06/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ocipgroup@klgates.com
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Office Action Summary	Application No. 10/598,978	Applicant(s) COHEN, DAVID I.	
	Examiner STUART W. SNYDER	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2010 and 5/26/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/2010 has been entered.
2. Claims 1-5 are pending and examined herein. Acknowledgement is made of amendment of claim 1 in Applicant's submission filed on 4/13/2010.

Election/Restrictions

3. Applicant's election without traverse of HIV tat as the species of tat to be examined in the reply filed on 11/20/2008 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Determining the numbers of dendritic cells (DCs) and regulatory macrophages (AREgs). The Examiner takes note of the amendment of claim 1 which recites, "wherein the relative numbers of DCs and AReg identifies an immunosuppressive NICE or an

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immunostimulatory NICE". However, the recited steps require only the determination of the "presence of DCs and AReg"; the method does not recite any step wherein the DCs and ARegs are enumerated. Thus, an essential step, enumerating both DCs and ARegs, is missing.

5. Claim 4 recites the limitation "method according to claim 2 wherein the said immunosuppressive mouse" in lines 1 and 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. However, claim 2 does not recite "immunosuppressive mouse". Claim 3 recites "immunosuppressed mouse". Furthermore, the meaning of "immunosuppressive" is different than "immunosuppressed"; in the former, the term suggests that the mouse would suppress immunological functions of other mice whereas the latter term suggest that the mouse suffers from a condition that reduces some function of the immune system.
6. Claim 5 recites the limitation "tolerogenic NICE" in line two of the claim. There is insufficient antecedent basis for this limitation in the claim; claim 5 depends on claim 1. Claim 1, in turn, is drawn to a method of determining the possible immunomodulatory effects of tat-like entities. The results of performing the method of the of claim 1 would be determining that the NICE would have immunosuppressive effects on PBMCs, immunostimulatory effects on PBMCs, or no immunomodulatory effect on PBMCs. The specification describes development of general and/or specific immunomodulatory effects including tolerance to general or specific antigens. However, tolerance is not a predictable

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function of the NICE but is discovered after discovery of the NICE. Furthermore, claim 1 does not recite results necessary to determine tolerogenicity. Thus, claim 1 does not provide an antecedent basis for the term "tolerogenic" or "tolerance".

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Cohen, Cohen, et al., Cheadle, et al., and Baghian, et al. is **withdrawn** in view of amendment of claim 1 and Applicant's arguments in the submission filed 4/13/2010.

Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on (571)272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

SWS